

EXHIBIT A

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

: EXAMINER: KAHELIN, MICHAEL
WILLIAM

INVENTOR: MOWER, MORTON M.

APPLICATION NO: 10/656,222 : GROUP ART UNIT: 3762

FILED: SEPTEMBER 8, 2003 :

FOR: METHOD AND APPARATUS FOR :
INTRACHAMBER
RESYNCHRONIZATION

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

Sir:

Dr. Morton M. Mower M.D. declares:

1. I have received a medical doctorate (MD) degree from the University of Maryland Medical School, and a Bachelor of Arts (BA) degree from the Johns Hopkins University. My area of particular expertise is Cardiology and Electrophysiology.

2. My current position is Associate Professor of Medicine at the Johns Hopkins University School of Medicine, and Professor of Physiology and Biophysics at Howard University College of Medicine.

3. I have been widely recognized in the field of Cardiology and Electrophysiology, including:

- The Space Technology Hall of Fame Recognition Award
- The Michel Mirowski Award of Excellence in the Field of Clinical Cardiology and Electrophysiology.

- The Medical Alley Award for Outstanding Contribution in Research and Development.
- The NASPE President's Award
- The University of Maryland School of Medicine Alumni Association Honor Award & Gold Key For Outstanding Contributions to Medicine and Distinguished Service to Mankind.
- The Distinguished Alumnus Award of The Johns Hopkins University.
- Career Achievement Award from Chiang Mai University.
- Inductee of the National Inventors Hall of Fame.

4. I am the named inventor of the above captioned patent application, and I am the named inventor on 37 US patents, also with numerous foreign counterparts, and my contributions to the medical literature includes about 350 articles.

5. I have thoroughly reviewed patent application 10/656,222 including the current claims submitted together with this declaration.

6. I have also reviewed the Official Action of March 30, 2009.

7. I have thoroughly reviewed the rejection applied to the current claims, including the reference:

- U.S. Patent Publication No. US 2003/0105496 to Yu (hereinafter "Yu")

8. Based upon my review of these materials and my background and experience in the field of Cardiology and Electrophysiology, I am of the following opinions:

9. Yu describes a system for providing cardiac resynchronization therapy (CRT).

The system utilizes accelerometers to optimize system performance by mechanical measurements of wall displacement. Yu at ¶¶ 24-26 Figs 1-3 describe the general components of the system. Yu is directed to inter-chamber CRT systems, including atrial and ventricular electrodes.

10. Yu does not describe pacing of the left ventricle only for intra-chamber synchronization as currently claimed.

11. The Office has noted at page 4 of the Official Action that although Yu is deficient in describing stimulation to the left ventricle only, but, states that such an arrangement is obvious noting: "*it is well known in the pacing arts to provide septal electrodes with screw-in tips that provide stimulation to only the left ventricle to provide the predictable result of reaching the desired chamber for pacing therapy without the accompanying thrombosis complications.*"

12. I do not agree with the thrombosis rationale presented in the Official Action as to the obviousness of the claimed features relative to Yu. The most straightforward method of pacing the left ventricle consists of pacing through a retrograde catheter placed within the left ventricle. In such a system, thrombosis complications exist regardless of lead placement. Pacing for the right ventricle is universally believed to reduce LV delay and Left Bundle Branch Block (LBBB). When a physician sees a different pattern such as Right Bundle Branch Block (RBBB) with RV pacing, the first thought is that the pacing tip has perforated, rather than having a desired specific chamber effect.

13. The septum separating the left and right ventricles consists of a mixture of left and right ventricular endocardium. The ratio varies in the various parts of the septum, and when the septum is paced, it most often results in a delay in left ventricular activation. Other pulses there are sometimes conducted to the left side in a very expeditious manner, often resulting in unusual patterns of conduction in the electrocardiogram. See Mower MM, Aranaga CE, and Tabatznik B: Unusual Patterns of Conduction Produced by Pacemaker Stimuli. Amer. Heart J 74:24-28, 1967. It has never been widely appreciated that in the mid-septum the right ventricular endocardium is particularly thin, and the surface of the right side of the septum is functionally left ventricle. Thus a pacing lead placed at the exact middle of the interventricular septum on the right side can oftentimes preferentially stimulate left ventricular myocardium and does not immediately affect the right ventricle.

14. I declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patent issuing from this application.



Dr. Morton M. Mower M.D.

Date

